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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,011 04/20/00 RANGANATHAN

N KBI-0003

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EXAMINER

PATTEN, P

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

08/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/557,011

Applicant(s)

Ranganathan et al.

Examiner

Patricia Patten

Group Art Unit

1651



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-7 _____ is/are pending in the application.

Of the above, claim(s) 5-7 _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a microencapsulated composition comprising a mixture of sorbents with affinities for uremic toxins and a bacterial source which metabolizes urea and ammonia, classified in class 435, subclass 262.5 for example.
- II. Claims 5-7, drawn to a method of alleviating symptoms of uremia in a patient by administration of a composition comprising a mixture of sorbents with a bacterium, classified in class 435, subclass 268 for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case urease has been shown to have a positive effect on individuals suffering from uremia.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Jane Massey Licata on 7/19/2000, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-7 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claims 1-4 have been presented for examination on the merits.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites 'middle molecular weight molecules.' This statement is indefinite. There are a myriad of middle molecular weight molecules in the body, and one of ordinary skill in the art would have trouble ascertaining what middle molecular weight molecules the claim is referring to.

Limitation to particular molecules is suggested in order to avoid confusion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yatzidis et al. (1979) in view of Prakash et al. (1995) and further in view of Goldenhersh et al. (1976). Claims 1-4 are drawn to a microencapsulated formulation comprising a mixture of sorbents and a bacterial source, wherein the sorbents have absorption affinities for substances such as ammonia, urea, creatine, phenols and indoles. Claims are further drawn to where the composition comprises a phosphate binding agent and a water binding agent.

Yatzidis et al. (1979) disclosed that locust bean gum showed a beneficial effect on patients with renal failure (uremia). Locust bean gum was shown to have the ability to absorb urea, creatine, uric acid, ammonia, phosphorus, chloride and sodium (pp.105). Locust bean gum also 'adsorbs about 10 times its own weight in water' (instant specification pp.4, lines 14-15). Yatzidis et al. did not specifically mention the combination of locust bean gum with a bacterium.

Prakash et al. (1995) disclosed a method for treating uremia by use of a microencapsulated E.coli strain (DH5) (Please see Abstract). They explained that the E.coli cells 'efficiently depleted urea' (pp.625 Col.1)) and further indicated that the same bacteria lowered overall ammonia levels (pp.625 Col.2).

Goldenhersh et al. (1976) discovered that there was a severe 'adsorption competition which interfered with adsorption of creatine on activated carbon'(pp.252 Col.2). They consequently found that a microencapsulated form of activated charcoal resulted in required less of an amount of the charcoal being administered (pp.253, Col.1).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to treat uremia. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been further motivated to have microencapsulated the composition comprising bacteria and absorbents because microencapsulation would have resulted in a lesser quantity of absorbents being used due to inhibitory mechanisms as discussed by Goldenhersh et al. It was further known that microencapsulated bacterium had a longer lasting effect as taught by Prakash et al. Hence, the ordinary artisan would have reasonably ascertained that a formulation for treating uremia had an improved beneficial effect when it was microencapsulated due to the competitive aspects in biological fluid.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

A handwritten signature in black ink, appearing to read "Jon P. Weber". The signature is fluid and cursive, with the first name "Jon" being the most prominent part.

Jon P. Weber, Ph.D.
Primary Examiner